DEPARTMENT OF HEALTH AND HUMAN SERVICES

and

CENTERS FOR DISEASE CONTROL AND PREVENTION

convene the

ADVISORY COUNCIL FOR THE ELIMINATION OF TUBERCULOSIS

Atlanta, Georgia
February 4-5, 2004

RECORD OF THE PROCEEDINGS

TABLE OF CONTENTS

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CENTERS FOR DISEASE CONTROL AND PREVENTION

ADVISORY COUNCIL FOR THE ELIMINATION OF TUBERCULOSIS
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Minutes of the Meeting

The Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) convened a meeting of the Advisory Council for the Elimination of Tuberculosis (ACET). The proceedings were held on February 4-5, 2004 at CDC's Corporate Square Facility, Building 8, in Atlanta, Georgia.

Opening Session

Dr. Masae Kawamura, the ACET Chair, called the meeting to order at 8:35 a.m. on February 4, 2004. She welcomed the attendees to the proceedings and opened the floor for introductions. The following individuals were present for the deliberations.

ACET Members
Dr. Masae Kawamura, Chair
Dr. Michael Fleenor
Ms. Teresa Garrett
Dr. David Gonzales
Ms. Harriett Gray
Ms. Sara Loaiza
Ms. Eileen Napolitano
Dr. Stephen Puentes

***Ex Officio*s and Liaisons**
Dr. William Baine (AHRQ)
Ms. Duiona Baker (SAMHSA)
Dr. Eric Blank (APHL)
Dr. Amy Bloom (USAID)
Dr. Henry Blumberg (IDSA)
Dr. James Cheek (IHS)
Ms. Fran Dumelle (ALA)
Dr. Miguel Escobedo
(U.S.-Mexico BHC)
Ms. Kim Field (NTCA)
Dr. Michael Kurilla (NIH/NIAID)
Dr. James McAuley (CCCS and IDSA)
Ms. Eva Moya (U.S.-Mexico BHC)
Dr. Gary Roselle (VA)
Dr. Diana Schneider (DIHS)
Ms. Rachel Stricof (APIC and HICPAC)
Dr. Theresa Watkins-Bryant (HRSA)

Designated Federal Official
Dr. Ronald Valdiserri,
Executive Secretary

CDC Representatives
Dr. Harold Jaffe, NCHSTP Director
Dr. Kenneth Castro, DTBE Director

Dr. Jose Becerra
Ms. Kathy Cahill
Ms. Viva Combs
Dr. Hazel Dean
Mr. Nickolas DeLuca
Ms. Thena Durham
Ms. Mollie Ergle (Contractor)
Ms. Paulette Ford-Knights
Ms. Maria Fraire
Ms. Judy Gibson
Dr. Timothy Holtz
Dr. Dale Hu
Dr. Michael Iademarco
Dr. John Jereb
Ms. Lauren Lambert
Dr. Mark Lobato
Ms. Lilia Manangan
Ms. Suzanne Marks
Mr. Scott McCoy
Dr. Eugene McCray
Dr. Mary Naughton
Ms. Anne O'Connor
Ms. Lydia Ogden
Ms. Kathryn O'Toole
Mr. Paul Poppe
Ms. Margie Scott-Cseh
Dr. Wanda Walton

Guests

Dr. Richard Fluck (NCET)
Mr. John Lewis (CNTC)
Dr. Randall Reves (NTCA)
Mr. John Seggerson (NCET)
Mr. Anthony Tran (APHL)
Ms. Ena Wanliss (Constella)
Ms. Christina Williams (NTCA)

Dr. Ronald Valdiserri, the ACET Executive Secretary, informed the participants that ACET meetings are open to the public and all comments made during the proceedings are a matter of public record. He asked the members to be mindful of potential conflicts of interest identified by the CDC Management Analysis and Services Office. Members who have a direct funding relationship or fiduciary interest in any topic scheduled on an ACET agenda should recuse themselves from voting or participating in these discussions.

Dr. Kawamura reported that in response to action items raised during the previous meeting, she sent two letters to the HHS Secretary in June and October 2003 to describe the federal funding gap for TB. She has received no response to date, but will continue to follow up with the HHS Secretary. She also sent a letter to the Congressional Black Caucus to raise awareness about TB health disparities among blacks. The three letters were distributed to ACET for review.

Update by the National Center for HIV, STD and TB Prevention (NCHSTP)

Dr. Harold Jaffe's report covered the following areas. First, the President signed CDC's FY'04 budget on January 23, 2004 with a total appropriation of $7.1 billion. Of the $1.3 billion allocated to NCHSTP, the Division of Tuberculosis Elimination (DTBE) received a $1.5 million increase, while the Global AIDS Program (GAP) accounted for the majority of increases across NCHSTP. The total TB budget in FY'04 will be ~$137 million with

DTBE's $1.5 million increase. Congressional conferees urged CDC to allocate $1 million of the DTBE increase "to partner with a private foundation uniquely qualified to test new TB vaccines implemented in a large-scale and community-based TB vaccine trial."

The overall federal budget reflects a "recission" or mandated reduction. Although CDC's FY'03 base funding decreased by a recission of 0.65%, DTBE grantees were not affected. Because recissions are cumulative, however, the reduced FY'03 budget is now subject to an additional decrease of 0.6% in FY'04. The recission will be applied to all NCHSTP programs and to TB, HIV and STD grantees.

Second, efforts are underway to recruit a new Division of AIDS, STD and TB Laboratory Research Director; Mr. Michael Melneck is currently acting in this position. Ms. Janet Cleveland is now serving as the Division of HIV/AIDS Prevention, Intervention, Research and Support Acting Deputy Director. Dr. Jaffe will be retiring from CDC in June 2004 to serve as the Chair of Public Health at the University of Oxford in England. The CDC Director will appoint an NCHSTP Acting Director while a search is conducted to permanently fill the position. Dr. Jaffe thanked ACET for consistently providing CDC with solid guidance and strong support. Dr. Kawamura led the participants in applauding Dr. Jaffe's involvement with and support of ACET during his tenure as the NCHSTP Director.

Update by the DTBE Director

Dr. Kenneth Castro's report covered the following areas. First, efforts are underway to recruit a new Clinical and Health Systems Research Branch Chief. Second, DTBE is supporting and closely collaborating with state and local TB programs to finalize 2003 TB morbidity data and report these findings at World TB Day on March 24, 2004. DTBE will also participate in the Stop TB Partners Forum in New Delhi, India. Third, contracts were issued to the California and Michigan Department of Health Laboratories to conduct universal genotyping of *Mycobacterium tuberculosis* (*M.tb*). Although fingerprinting of *M.tb* will be performed at no cost to state health departments that submit samples to the California and Michigan laboratories, the contracts do not cover mailing costs.

In response to a program announcement, 31 states were approved to conduct universal genotyping. One state will perform selected routine genotyping of targeted populations, while the other 30 states will fingerprint all culture-positive individuals. Fourth, a deficit is projected for DTBE's FY'04 budget due to elimination of unobligated funds at year-end; improved initial and out-year cost plans; convergence of relatively costly projects; salary increases mandated by the Office of Management and Budget; and modest

earmarked increases. Plans to redistribute the FY'05 budget during the re-competition of the TB cooperative agreement will continue and assume level funding.

Of the TB grantees, 21 will receive reduced funding, 31 will receive increased funding, and 14 that receive ≤$200,000 will not be affected. The redistribution of funds is calculated based on the types of issues grantees target, such as overall TB morbidity, the homeless population, U.S.-born persons, minority groups, foreign-born individuals and HIV-infected patients. Using the Consumer Price Index to compare federal TB dollars in 1990 and 2004, the data show that the purchasing power has consistently eroded. In 2002, the National Coalition for the Elimination of Tuberculosis (NCET) commissioned a funding gap analysis that showed $528 million is needed each year to implement the Institute of Medicine (IOM) recommendations and eliminate TB. NCET has now commissioned an update to the 2002 analysis.

Fifth, the Occupational Safety and Health Administration (OSHA) formally rescinded its rule-making for occupational exposure to TB on December 31, 2003. OSHA is now proposing rule-making in which assigned protection factors (APFs) would be used to select personal respiratory protective devices. The proposed rule is unclear due to the common misconception that APFs apply to infectious particles. Because minimum concentration exposures have not yet been calculated, CDC has urged OSHA to clarify that APFs are intended for chemical and other environmental toxins and do not apply to infectious particles.

The December 2003 *Federal Register* notice stated that OSHA would apply the general industry respiratory protection standard (GIRPS) to the control of occupational exposure of *M.tb*. However, the GIRPS is limited to general industry, shipyards, marine terminals, long-shore activities and construction; other infectious agents and exposures to patients are not covered. The GIRPS was specifically developed for hazardous substances from airborne contaminants and chemical toxins with minimum-use concentrations and maximum exposure levels.

ACET noted that although the proposed TB rule was withdrawn, OSHA will now impose GIRPS requirements on occupational TB exposure which include initial fit testing, respirator use, specific medical assessment tools, and annual fit testing. Despite the expertise, success and effectiveness in controlling TB in health care facilities, OSHA will now apply the GIRPS rule to all settings with potential occupational exposure to TB. Overall, OSHA's GIRPS rule is not scientifically justified and will impose a tremendous burden on the health care delivery system. Unlike other proposed rules in which a public comment period is opened, OSHA explicitly stated that the GIRPS rule is effective immediately and health care facilities will be given six months for implementation.

CDC made remarks to address ACET's concern. The revised TB infection control guidelines were distributed to ACET for review and are now being cross-cleared and finalized within CDC. Major substantive changes were not made to the guidelines; instead, the revisions primarily focus on consistent language, accurate references or citations, and similar editorial modifications. Most notably, CDC did not change the "initial and periodic fit testing" language in the revised guidelines. CDC confirmed that ACET will have an opportunity to provide input when the revised guidelines are published in the *Federal Register*.

Overview of the CDC Futures Initiative

Ms. Kathy Cahill, the CDC Senior Advisor for Strategy and Innovation, described efforts that have been undertaken for the activity to date. The Futures Initiative was launched in June 2003 because CDC had not developed an agency-wide strategic plan for over ten years. The activity is designed to improve and measure CDC's impact on public health and the health status of individuals in the United States. CDC's "outside-in" approach to gathering input for the Futures Initiative is interactive, data-driven and focused on customers.

For "customer" input, CDC administered surveys to the general public, taxpayers or others who directly or indirectly receive CDC's services. The data showed the following results. All public groups were concerned about chronic diseases and rising health care costs, but very few customers were aware of CDC's capacity in injury prevention, chronic diseases and occupational safety and health. Public recognition and knowledge of CDC were primarily limited to the agency's expertise in infectious diseases and emergency preparedness. CDC was not spontaneously mentioned as a source to obtain health information; customers were more likely to rely on the Internet, health care providers or the media. Customers viewed CDC as a scientifically-driven and respected health organization, a leader in the public health field, and a credible voice for health information. The public also recognized CDC for its expertise and roles in research, infectious and communicable diseases, health statistics and health trends.

For "partner" input, CDC administered surveys to educational groups, the media, community-based organizations (CBOs), policymakers, the private health community, insurers, businesses and the public health community. The data showed the following results. Partners viewed CDC as a valuable, highly respected and credible agency. Several respondents believed CDC should play a lead role in establishing a public health agenda and defining prevention priorities, while others felt CDC's role should be limited to a "convener."

Partners acknowledged that CDC will be challenged in balancing emergencies and high-profile needs with long-term and ongoing public health issues. Partners advised CDC to enhance support for and investment in the public health infrastructure at state and local levels. Partners constantly expressed frustration with "silos" in terms of the difficulty in understanding CDC's organizational structure and obtaining assistance from the appropriate center, institute or office (CIO). Partners also noted that CDC's silos hinder communication and limit the effectiveness of public health efforts. Some partners viewed CDC as too academic in nature or "arrogant." State and local health departments would be better served if CDC took an actual practice, application or translation approach in providing assistance.

Partners advised CDC against excluding or abandoning state and local health departments, but recommended that partnerships with these traditional groups be expanded. A coordinated strategy should be developed with the overall health care delivery system to include health plans, educational organizations, businesses, minority groups, national organizations, CBOs and environmental groups. Partners acknowledged that CDC's key products and services include a world-renowned disease tracking and surveillance system; the best-trained epidemiologists in the world; funding, capacity building and other assistance to state and local health departments; information and guidance in emergency response and preparedness; and best practices in disease prevention and control.

In addition to gathering input, CDC also established three Futures Initiative workgroups to focus on critical issues. First, the Health Systems Workgroup took a broad sector approach in identifying improvements that can be made to the current health system. The workgroup reviewed the governmental public health, health care delivery, education, transportation and business sectors in making the following recommendations. CDC currently has a disease orientation, but this focus should expand to health. For example, CDC should take a life stage approach in designing and directly distributing health information targeted to individual health needs. CDC currently develops and implements sponsored programs, but this activity should expand to providing information and guidance to health care providers.

CDC currently allocates resources, but this effort should expand to leveraging resources. For example, CDC should establish national health policies and convene appropriate groups to drive a public health agenda. CDC currently collects and analyzes health data, but this initiative should expand to creating integrated health information systems. For example, CDC should play a lead role in incorporating public health information into electronic medical records, clinical laboratory data and health plans.

CDC should effectively integrate prevention in the health system by broadly marketing prevention; communicating a strong business case for prevention; coordinating prevention throughout the continuum of care; and targeting prevention to address social, behavioral and environmental determinants of health. Some of these issues can be addressed by conducting studies to demonstrate the effectiveness, benefit, value and cost of prevention to businesses and the health care system. CDC should highlight public health as an effective partner in prevention efforts by enhancing the workforce, improving information systems and ensuring organizational capacity. Some of these issues can be addressed by stronger efforts to recruit, retain and certify the workforce and strategies to develop accreditation and performance standards for the public health infrastructure.

Second, the Research Workgroup acknowledged that research is essential to CDC's mission and is primarily driven by population health, CDC goals and program needs. The workgroup identified several items that will be necessary for CDC to strengthen its research initiatives in the future: a better extramural peer review process with additional resources; external input to develop an agency-wide research agenda; enhanced collaboration and coordination with the National Institutes of Health (NIH); a balanced portfolio of CDC's intramural and extramural research programs; a stronger applied research program; consistent research processes across programs; a credible peer review process; and workforce development.

Third, the Global Health Workgroup recognized that CDC's dominant role is to protect the health of all U.S. citizens, but the agency must also lend its expertise to other countries. The workgroup made several recommendations for CDC to expand its global capacity. CDC should continue to assist countries in developing and sustaining public health systems and preventing and controlling high-priority diseases. CDC should collaborate with international partners to build skills, tools and networks to support in-country efforts. CDC should review its ability to respond to global challenges and threats on an ongoing basis. Efforts are underway to address some of the workgroup recommendations. In FY'04, the CDC Office of Global Health and other CIOs will identify mechanisms to coordinate training, development of laboratory capacity, surveillance and detection at the global level.

At this point, CDC is still gathering input that will be used to transform activities throughout the agency to meet the demands of customers and partners. The feedback is a critical component of the Futures Initiative and will assist CDC in generating agency-wide goals, objectives and activities for future implementation. Although the Futures Initiative is still ongoing, CDC has developed several strategies to respond to input gathered to date. The public health system will be revitalized and refined with a particular focus on infrastructure needs of state and local health departments. CDC's marketing and communication capacity will be enhanced and used as a tool in public

health intervention. CDC's partnerships with state and local health departments and other appropriate entities will be strengthened to more broadly deliver messages and rapidly disseminate information to customers.

CDC will continue to build its public health research and scientific capacity and will also increase its global health impact. CDC will redesign and streamline its accountability and organizational structure to support new strategic directions. This effort will be undertaken by improving current business practices for recruiting and hiring staff, managing grants and contracts, maintaining skills in information technology, and building a workforce and skill sets for the future. CDC will articulate and broadly advertise its goals and strategies, take actions to address new directions, and measure impact to demonstrate effectiveness in health trends.

In terms of the Futures Initiative time-line, CDC will establish major health goals and strategic directions, evaluate organizational structure and needs, and review global efforts over the next two months. CDC will then make critical organizational changes and begin to implement Futures Initiative strategies, such as developing a research agenda, designing a global strategy, creating a rapid and effective health communications process, and addressing the Health Systems Workgroup recommendations. Over the next year, CDC will develop agency-wide benchmarks that will be used to annually measure the impact of the Futures Initiative strategies, make necessary changes and identify new directions.

CDC announced that Dr. Kawamura and other CDC advisory committee chairs serve on a workgroup to advise the CDC Director on the Futures Initiative. ACET made several suggestions for Dr. Kawamura to raise during the workgroup meeting on the following day.

- Leadership. CDC should be mindful of the current environment in which an organization views itself as the expert for a particular chronic disease and releases guidance that conflicts with other groups. CDC should make efforts to ensure that messages, published guidelines and other health materials are consistent among organizations.

- Support. CDC should be aware that the Futures Initiative may be widely embraced in theory, but may not be actually understood or supported by policymakers and other political leaders due to other health and fiscal priorities. To obtain endorsement and support at the highest levels, CDC should consider the Futures Initiative as a long-term endeavor.

- Partnerships. CDC should highlight a collaborative effort in the Futures Initiative that serves as an excellent example of partnership among

diverse organizations and has led to a dramatic decrease in gaps among the groups. In this model, the CDC Division of Diabetes Translation, the Health Resources and Service Administration (HRSA), academic institutions and private foundations partnered to improve health outcomes for diabetic patients. The Futures Initiatives and the 2004-2008 National Strategic Plan for TB Training and Education are consistent in identifying the need to involve national agencies, organizations and other new or non-traditional partners outside of the public sector. The two activities present a joint opportunity to broaden the public health focus beyond the need to increase the budget. The Futures Initiative is targeted to customers, but the general public should not be allowed to set CDC's research agenda. CDC must maintain its strong partnership with the local public health community

- Communication and Marketing. CDC should use full names for acronyms with more than three letters because longer terms create communication barriers for external partners and stakeholders. CDC should acknowledge and be prepared to respond to public concern that the Futures Initiative will change the agency's mission. For example, some customers may believe CDC will no longer focus on anthrax, TB or other diseases beyond individual control because the agency will concentrate on obesity, heart disease or other conditions that can be managed with lifestyle changes.

  CDC must conduct business differently to reach other audiences beyond traditional health partners. For example, health departments are used as the route of communication between CDC and programs, but this mechanism will not be appropriate for direct interaction with practicing physicians and consumers. CDC's efforts to personally communicate with individual program staff and other providers in the field have decreased over the years. Although CDC releases a wealth of information through its web site and written communications, programs still need direct interaction and dialogue with CDC staff to accurately interpret and apply data.

In addition to these suggestions, ACET also asked Dr. Kawamura to convey general comments during the Futures Initiative workgroup meeting. CDC is commended for developing the Futures Initiative, broadly soliciting input, and seeking extensive participation from partners at state, local and national levels as well as non-traditional stakeholders. In addition to communication and marketing efforts to new audiences, CDC should still maintain its solid track record in disseminating factual information to health departments and programs. The frustration of partners with CDC's silos should be noted as a Futures Initiative priority. Most notably, many local programs perceive CDC as an "ivory tower" that does not effectively apply local expertise and knowledge

throughout the agency. Public excitement about the release of the Futures Initiative and implementation of new strategies may result in less emphasis on TB and other public health priorities that have been on CDC's agenda for quite some time.

CDC described several actions that will be taken to address ACET's suggestions and comments. With respect to support, CDC will take a "segmentation of the population" approach in the Futures Initiative by rigorously focusing on U.S. demographics. For example, TB activities, messages, information and programs would be targeted to audiences in most need. CDC will be more likely to generate long-term support for the Futures Initiative by implementing a demographics strategy. In terms of communications and marketing, CDC realizes that many customers view the Futures Initiative as a mechanism for the agency to shift from infectious to chronic diseases. However, the public will be informed at every opportunity that CDC's infectious disease capacity is the basis for its recognition, credibility and knowledge. CDC's expertise in this area will also serve as the foundation to expand to other areas in the future; current public health issues will not be abandoned.

CDC acknowledges that communicating with different audiences beyond public health departments will be a major challenge throughout the agency. In the future, CDC must improve its ability to rapidly distribute accurate health data to a variety of audiences since customers now receive information from the Internet and 24-hour news programs in nearly real time. New strategies and partnerships must be developed for CDC to quickly exchange information in this environment. Instead of partnering with one channel, for example, CDC will collaborate with several networks of professional health associations and other groups that can directly market to and communicate with providers and the public.

CDC is currently exploring the possibility of detailing more staff to state and local health departments to increase one-on-one communications with programs. For example, consideration is being given to incorporating a peer exchange process into the workforce development plan that is being created under the Futures Initiative. In response to ACET's general comments, CDC clarified that the Futures Initiative is not intended to focus on "popular" issues. Instead, the activity is being designed to build CDC's organizational structure to increase new partners; more rapidly disseminate health information on prevention; and enhance communication, research and surveillance capacity.

CDC is aware that partners are frustrated by silos, but caution must be taken in changing this area. On the one hand, CDC realizes that its organizational structure must be accessible and sufficiently transparent for partners to easily obtain information. On the other hand, CDC's current framework is necessary because each silo is designed to be disease-specific, produce credible science and develop solid programs.

Moreover, changes in silos should be consistent with the IOM recommendation to maintain categorical funding for certain diseases. For example, a resurgence in TB was seen after the TB silo was removed in the 1970s and block grants were used. To retain CDC's focus on TB during the release and implementation of the Futures Initiative, ACET and other TB partners should thoroughly review the new strategies to ensure that TB and other public health issues with a disproportionate burden to specific populations are included.

Update on TB Prevention and Control in Correctional Facilities

Dr. Mark Lobato of DTBE reported that ACET and the Division of Immigration Health Services (DIHS) extensively focused on inmates being released from Bureau of Immigration and Customs Enforcement (ICE) detention facilities. Outcomes from these deliberations led to a published article in the *Morbidity and Mortality Weekly Report* (*MMWR*) and the establishment of a policy workgroup represented by CDC, DIHS, ICE and state and local health departments. In developing an action agenda for this issue, the policy workgroup determined that the 1996 guidelines for TB prevention and control in correctional facilities were inadequate in many aspects. The policy workgroup then proposed that ACET and CDC consider updating or revising the 1996 recommendations. An ad hoc advisory group represented by correctional facilities, federal agencies, TB programs and the private sector was formed for this effort.

The ad hoc advisory group reviewed the 1996 recommendations to fulfill its charge and noted several limitations. For symptoms screening, many facilities are not asking appropriate or specific questions at intake. Due to high turnover among corrections personnel, staff should be trained on an ongoing basis in techniques to use during screening interviews. This issue is particularly important since symptoms screening is the first line of defense in protecting against TB transmission among inmates and corrections staff.

For TB testing or diagnostics, the 1996 recommendation to test within 14 days in high-prevalence jurisdictions may be excessive, but the ad hoc advisory group did not reach consensus on the best approach to take. Some members suggested that a menu of options be offered, such as symptoms screening and the QuantiFERON (QFT) TB test. However, the role of the QFT-TB test in correctional facilities is unknown at this point due to the lack of supporting data. Routine TB testing is performed to detect cases, but latent TB infection (LTBI) is more likely to be found. As a result, the failure rate in completing LTBI therapy may be high in correctional facilities.

For environmental controls, clear guidance is needed for administrators and medical directors, but recommendations should also extend to architects, engineers and other

designers as new facilities are built. For respiratory isolation, stronger and more specific language or algorithms are needed to provide guidance on when to release inmates from isolation or medical holds. For treatment, the language on LTBI and treatment should be updated with more recent data published over the last two years. Guidance for case management and discharge planning should be improved as well. For collaboration, general language in the 1996 guidelines to conduct contact investigations with health departments is weak. The two groups are still undertaking independent and separate efforts; the need to refer soon-to-be released inmates is not mentioned. The guidelines should strongly emphasize the need for close collaboration between the health department and correctional facility.

Based on its review of the 1996 guidelines for TB prevention and control in correctional facilities, the ad hoc advisory group definitively concluded that the recommendations should be revised. A group of correctional and non-correctional representatives with expertise in TB and infection control has been assembled to advance this effort. The group has been divided into eight teams to specifically address screening, environmental controls, therapy, discharge planning, contact investigations, training and education, evaluation and collaboration. Each of the eight teams is led by a CDC and non-CDC staff member.

Over the next 12 months, the eight corrections teams plan to review the current literature; update the 1996 guidelines; obtain ACET's participation in reviewing the revised guidelines; and finalize the document for clearance and publication. However, the group is limited to e-mail communications and telephone conferences at this point. No travel funds or other resources have been allocated to perform the planned tasks, such as convening a face-to-face meeting or presenting the updated guidelines to the National Tuberculosis Controllers Association (NTCA) and correctional groups. CDC is now asking ACET to determine whether additional experts should be invited to serve on the corrections teams and if ACET members will be willing to review the revised guidelines.

ACET made several suggestions for the corrections teams to consider. First, every effort should be made to obtain funding to publish and widely disseminate the updated guidelines because the recommendations will have implications at county and local levels. State and federal institutions will be less effective in improving TB prevention and control if smaller jails do not actively implement the guidelines as well. Second, "delays in diagnosis" should be assigned to one of the corrections teams. This issue is particularly important in county jails because the facilities frequently have TB transmission from highly susceptible inmates, but fail to investigate the cases.

Third, "infection control" and "engineering control" should not be interchangeably used. Infection control broadly covers initial screening, ongoing evaluation, safe identification

of individuals, and the release of TB cases to the general population. Fourth, strong efforts should be made to obtain agreement and endorsement of the revised guidelines from both public health and correctional groups, including CDC, ACET, the American Thoracic Society (ATS), Infectious Disease Society of America, American Correctional Association (ACA) and National Commission on Correctional Health Care (NCCHC). The 3,500 county jails in the United States may be more likely to implement the guidelines if these groups reach consensus. The updated guidelines should also be incorporated into the next revision of correctional standards developed by ACA, NCCHC and ICE detention facilities. The corrections teams should consider ACET as a mechanism to bridge the gap between health departments and local jails.

Fifth, guidance should be developed to clearly outline the role and responsibilities of state health departments in implementing the revised recommendations, such as compiling epidemiological information or encouraging program staff to strengthen partnerships with correctional facilities. Sixth, the corrections teams should be mindful of costs since many local jails will be unable to implement the revised guidelines due to budgetary constraints.

CDC provided additional details on issues the corrections teams will address. Reduction in TB transmission will be a broad focus area, but the revised guidelines will emphasize the need for ongoing training and guidance of corrections staff to sustain long-term improvement. Data gaps that need to be filled will be another key topic since the revised guidelines can assist in formulating future research priorities. Cost will be discussed, but this issue should not be a major barrier for most facilities due to the simple measures being recommended, such as symptom screening during intake. Moreover, if the revised guidelines are issued with full endorsement by ACA and NCCHC, jails will then have strong justification to obtain funding for implementation.

CDC is pleased the ad hoc advisory group recommended a revision of the 1996 guidelines due to the U.S. Surgeon General's call to action for correctional health. The U.S. Surgeon General will review and clear a draft outline of the call to action; a federal partners meeting will be held on February 20, 2004 to discuss the document; and the approved draft outline will be presented to external partners. Because TB is included in the initiative, infection control experts and TB groups should be extensively involved with the development of the call to action. A follow-up workshop to the federal partners meeting will be held in late spring 2004; the final call to action is expected to be produced by July 2004. Overall, CDC confirmed that resources should not be an issue in revising, publishing and widely distributing the guidelines, particularly since surveillance data show that local and county jails account for the majority of TB cases reported from correctional facilities.

ACET placed a motion on the floor to formally accept the ad hoc advisory group's recommendation to revise the 1996 guidelines for TB prevention and control in correctional facilities. ACET further stated that it will provide input for the group to consider and may also designate members to serve on the corrections teams. The motion was properly made and seconded by voting members and was **unanimously approved** with no further discussion.

TB Behavioral and Social Science Research Forum

Mr. Nickolas DeLuca of DTBE announced that the Forum was held on December 10-11, 2003 to identify and prioritize TB behavioral and social science research gaps. Outcomes from the Forum will contribute to the development of a research agenda to assist the U.S.-based research community in guiding TB behavioral and social science research. To support this effort, the published TB behavioral and social science literature is being systematically inventoried and reviewed; a database is being created; workgroups are being established based on initial Forum themes; and a behavioral and social science list-serv is being created for ongoing discussion and information exchange.

A TB behavioral and social science workshop was convened in 1994 to establish a research agenda for this issue. Efforts have been made over the past ten years to address issues raised during this event, but many activities are still outstanding. For example, in its *Ending Neglect* report in 2000, the IOM underscored the need to conduct studies to determine the role of basic behavioral theories in enhancing understanding of creating tailored interventions for high-risk populations. The 2003 Forum served as an effort to revisit the 1994 issues and identify changes that have occurred in TB prevention and control since the initial workshop, such as a different TB epidemiology, increased TB among foreign-born persons, and a stronger emphasis on LTBI identification and treatment.

To obtain diverse input, over 60 TB prevention and control representatives from a variety of areas attended the Forum, including researchers from academic institutions and organizations, TB program staff, patients, health care workers, CDC, NTCA and Model TB Centers. Presentations at the Forum focused on examples of behavioral and social science research, the need for these types of studies from a TB program perspective, and findings from a preliminary literature review. Panel discussions covered TB from patient and health care worker perspectives as well as the translation of research into practice. During interactive breakout sessions, perceived research gaps, research questions and proposed methods were identified. Responses from the participants will be matched to findings from the literature review. The participants identified five preliminary gaps.

First, provider knowledge and practices are issues of concern that should be examined on an ongoing basis. Stronger efforts should be made to engage private providers; more emphasis should be placed on the role of culture and training in provider practices; communication between providers and patients should be enhanced; and research should be proposed to increase awareness of and adherence to CDC and ATS guidelines. The participants identified health seeking behavior, adherence, the role of culture, and competing health and social needs as key gaps for patients.

Second, health systems and organizational issues should be strengthened by improving contact investigations; exploring the role of incentives and enablers in treatment and adherence; examining the effectiveness of case management; and enhancing collaboration between provider communities, particularly HIV and TB physicians. The participants identified insurance status and immigration status as major policy implications. Third, additional research should be conducted to better understand and address influences of social networks, family, knowledge, attitudes, and social stigma.

Fourth, more attention should be given to special populations, particularly foreign-born persons, migrant workers, homeless individuals and inmates/correctional staff. Fifth, methodologies should be designed to advance beyond descriptive or exploratory research; conduct more intervention studies based on behavior change theories and models; test the effectiveness of interventions; and translate research into practice. In follow up to the Forum, conference proceedings will be finalized, the literature review will be completed, the behavioral and social science list-serv will be developed, workgroups will be established to more closely focus on Forum themes, and the overall research agenda will be finalized for the FY'05 funding cycle.

The full conference proceedings will contain more details about the Forum outcomes. For example, the participants most frequently mentioned foreign-born persons, migrant workers, homeless persons and correctional groups as special populations for TB, but TB among blacks in the Southeast and TB disparities in other racial/ethnic groups were discussed as well. The full conference proceedings will also reflect the participants' deliberations on research questions and hypotheses that can be generated for future research. Recommendations from the 1994 workshop will be used to guide the current literature review and determine whether these issues were addressed and are reflected in more recent data. The 1994 recommendations and outcomes from the 2003 Forum will be compared to identify differences and assess effectiveness in implementing these issues over the past ten years.

ACET was impressed by the informative and extremely important Forum, particularly since the meeting served as a platform for CDC to obtain external input from TB patients, outreach workers, researchers and other groups. The Forum also facilitated

an opportunity for TB programs to network with researchers. ACET urged CDC to consider holding similar events on a more regular basis.

U.S.-Mexico Border Health Projects

Overview of the U.S.-Mexico Border Health Commission (BHC). Ms. Eva Moya is an ACET liaison representative for BHC. She explained that BHC's mission is to provide international leadership to optimize the health and quality of life of nearly 13 million residents along the U.S.-Mexico Border. BHC's goals are to institutionalize a domestic focus on Border health that can transcend to political changes and also to create an effective venue for binational discussion in addressing public health issues. BHC has recognized TB as a top priority for its agenda. After a U.S. public law was created and signed to establish BHC, the United States and Mexico agreed that BHC's role would be to promote social and community participation; serve as a catalyst for needed change; act as a policy advocate; increase resources for the Border; and encourage self-responsibility for health.

BHC's structure includes two sovereign nations, ten Border states, 44 counties, 80 municipalities, 14 pairs of sister cities, 26 BHC members, an interagency action team and core partners. BHC is supported by appropriations from both the United States and Mexico. Although the two countries allocated $5 million to BHC in FY'04, the funding is extremely low in light of nearly 13 million Border residents. Ideally, BHC would be funded with no less than $10 million per year to significantly impact Border health problems, including education, water quality, housing and insurance coverage. To date, BHC has approved its internal bylaws, implemented operational structures, increased Border and binational collaboration, developed a work plan for the U.S.-Mexico Border region, allocated funding to ten states in support of Healthy Border Plan activities, appropriated dollars for the Binational TB Case Management Program, and gave Border Model of Excellence awards to acknowledge best practices in Border health initiatives.

In addition to these milestones, BHC is also involved with several other projects. The Department of State (DOS) is considering BHC's application to be recognized as a public international organization. BHC is currently developing a Border health information network and geographic information system (GIS) mapping. HHS recently awarded $5.5 million for BHC to take a lead role in developing and implementing the U.S.-Mexico Early Warning Infectious Diseases Surveillance Project (EWIDSP). Funding for the project will be targeted to laboratory capacity, data reporting, health professionals training, and communications and technology. Because EWIDSP will be conducted across the Border and in five sub-regions, 90% of funding will be allocated to Mexico Border states An EWIDSP ad hoc committee will be established to address the public health infrastructure.

BHC's key partners include HHS, CDC, HRSA, Department of Energy, Pan American Health Organization, Border state health departments and other international organizations. However, plans are underway to increase these partnerships in 2004. BHC has published and disseminated *Healthy Border 2010* as an agenda for improving health along the Border. The document outlines TB and 19 other health objectives BHC has made a commitment to improve over the next six years. The publication reflects collaboration and agreement among the United States, Mexico and ten Border states. *Healthy Border 2010* is a living document that will be enhanced in the future by companion materials.

Outreach offices in both the United States and Mexico have increased BHC's presence and capacity in the Border region to address health needs in a binational and bilateral manner. The outreach offices serve as a critical resource to BHC in terms of training, capacity building and networking at the community level. The outreach offices are charged with promoting the *Healthy Border 2010* agenda; complimenting the mission of each state health department; ensuring that the BHC mission and outreach plans are implemented; and administering BHC resources. Outreach offices in Arizona, California, New Mexico and Texas are responsible for addressing immunization, TB and other infectious diseases.

BHC has planned several activities in 2004 to support *Healthy Border 2010*. Progress will be reviewed and objectives will be monitored with ongoing evaluation. The first bilingual and Border-wide behavioral risk factor surveillance system will be launched in partnership with CDC. A request for applications (RFAs) will be issued for the Healthy Lifestyles/ Chronic Disease Prevention and Control Initiative in collaboration with CDC. Statistical and program evaluation workshops will be held to provide training and technical assistance. An 18-month calendar for 2004-2005 was distributed to increase promotion of health messages in the context of HHS, CDC and HRSA priorities as well as key community interests, including World TB Day, the TB binational health card and U.S.-Mexico Border Binational Health Week.

In terms of information technology, BHC is continually improving its web site and has used video conferencing to communicate with agencies and other partners in a cost-effective manner. BHC plans to complete the *Healthy Border 2010* GIS mapping system in 2004 and implement a virtual private network for secure and reliable web-based communications. Cross-Border transfer of medications, specimens, health professionals and other goods will be another priority for BHC in 2004. Many patients do not receive care because a legal, efficient and effective process has not been developed to date for bi-directional exchange of goods. Efforts will be made to assemble stakeholders representing customs, immigration and security agencies to identify problems and resolve these issues.

Overview of Ten Against TB (TATB). Dr. Miguel Escobedo is an ACET liaison representative for BHC. He reported that TATB was created by state health directors in June 1995 as a Border-wide initiative to enhance binational control efforts. TATB is organized with a secretariat and several committees, but sister states ensure that Border activities are completed. Private organizations and agencies at federal, state and local levels in both the United States and Mexico attend TATB committee meetings that are convened throughout the year. TATB is charged with enhancing TB control efforts on both sides of the Border through binational collaboration, goal-oriented action and respect for existing programs. TATB's focus areas include epidemiology, surveillance, case management, laboratory capacity, training, health promotion, and resource acquisition.

To date, TATB has acquired and delivered medication, supplies and equipment; sponsored several training events; enhanced awareness of Border TB issues; and assisted with the design and implementation of the binational TB card, binational case management system and referral network. In the future, TATB will attempt to maintain its autonomy while enhancing collaboration with BHC and other binational organizations. TATB will clarify its organizational structure in the context of BHC as well. For example, TATB will function as the technical advisory body to BHC; partner with BHC to address barriers to effective binational TB control; and develop a five-year action plan to assist in guiding BHC efforts.

BHC and TATB are requesting assistance in the following areas to advance Border health activities. First, ACET could provide BHC with input and expertise during the implementation of Early Warning Infectious Disease Surveillance Project (EWIDSP) since TB is included as one of the infectious diseases. Second, ACET could more broadly distribute *Healthy Border 2010* to states, organizations and other constituents. Third, ACET could convey to the HHS Secretary the critical need to address cross-Border transfer of needed medical goods. Fourth, DTBE could encourage the CDC Director to visit the Border region in 2004 to allow BHC to showcase activities that will eventually benefit the health status of the nation.

Fifth, ACET could assist TATB in addressing barriers to effective binational TB control. Sixth, DIHS could play an important role in BHC and TATB epidemiology and surveillance projects being developed, such as serving on the EWIDSP technical committee that will be established. DIHS could also ensure that its electronic medical records system currently being created is compatible with BHC and TATB data systems. Information exchange with DIHS will be critical for BHC and TATB because DIHS is often the first health care provider for illegal aliens who enter the United States. As a result, DIHS has opportunities to identify TB and other infectious diseases early.

Laboratory Capacity to Support TB Elimination

Dr. Eric Blank is the ACET liaison representative for the Association of Public Health Laboratories (APHL). He conveyed that the IOM report charged APHL with evaluating the role of regionalization in the TB elimination effort in the context of stronger laboratory capacity. In response to this request, APHL used CDC cooperative agreement funds to convene a task force in October 2002. The task force was represented by APHL, CDC, NTCA and clinical laboratories and was asked to develop recommendations and draft a report outlining a framework for integration, collaboration and leadership of TB laboratory services. In fulfilling its charge, the task force first identified six major challenges for TB laboratories.

First, case rates have declined due to reduced competencies in low-incidence areas, non-compliance at the local level to follow the "level of service" concept, and contentious regionalization proposals. Second, the shift in public health priorities has resulted in reduced categorical funding for TB laboratories and increased support for responses to anthrax, bioterrorism and other crises. Third, increasingly complex technologies have required significant capital investments and the need to continually train and educate staff and users of TB laboratory services. Fourth, demands for high-quality services have contributed to budget cuts at federal, state and local levels and competing roles of public versus private laboratories. Fifth, key roles of public health laboratories have eroded because private laboratories now provide ~80% of initial laboratory services to diagnose TB. Sixth, despite advances in laboratory methods, lack of coordination in referring specimens and cultures continues to lead to unnecessary delays in laboratory testing, reporting and initiation of treatment.

The overarching goal of the task force in formulating recommendations and drafting a report was to improve TB control through optimal use of laboratory services and effective data reporting and tracking. The task force also identified several principles to guide its deliberations. Public health is imperative to eliminating TB. Critical issues are necessary for effective TB control, such as an integrated system with clinicians, laboratories and TB controllers; an effective partnership network of public and private laboratories; and a timely and complete communication process among the laboratory network, TB control programs and health care providers. Public health laboratories must take a leadership role in developing the network and facilitating communication. Each jurisdiction must ensure access to quality TB testing as well as complete and timely reporting.

The guiding principles led to the task force designing a changing paradigm for public health laboratories. Instead of surrounding the patient with a clinician, laboratory and public heath agency, for example, the laboratory would be the focal point to more effectively support the patient. The need to take a jurisdictional approach was another

major topic in the task force deliberations because each area will ultimately determine its best and most effective model. The task force created three benchmarks for jurisdictions to consider.

The first benchmark asks jurisdictions to conduct a comprehensive assessment of TB laboratory services in several areas: level of training available for clinicians, laboratorians and other health care providers; existing systems to transport specimens; quality of information flow between the private sector and public health laboratories or TB control programs; number of laboratories and level of service provided; and turnaround time for smears, cultures and sensitivity testing.

The second benchmark asks jurisdictions to evaluate actual costs of TB laboratory services. All payment sources from federal and state agencies, Medicaid/Medicare and the private sector should be included in the cost assessment. The third benchmark asks jurisdictions to develop a systems approach strategic plan to ensure quality, proficiency, adequate training, timely flow of information, appropriate use of new technologies, and a repository of isolates and fingerprinting capability. The strategic plan should include guidelines to assist laboratories in determining the appropriate level of service and recommendations to report and track information. The three benchmarks are consistent with the Federal Response Plan.

The task force was mindful of several outcome measures during its deliberations. The report should focus on the *Healthy People 2010* objectives to eliminate TB with a case rate of 1/1 million and identify TB in a two-day turnaround time. All newly diagnosed infectious TB cases should be started on appropriate treatment within 48 hours of specimen collection. Smear, culture and sensitivity testing should be conducted in accordance with current recommendations. Specific procedures should be written for interacting with TB control partners and facilitating the timely flow of information. Training outcomes should be measured.

The task force's report describes the Fast Track model, networks, consolidation and other examples of collaboration and coordination undertaken by jurisdictions to address referrals, liquid culture and other laboratory issues. The report also acknowledges the ongoing need for operational and applied research in supporting science- and experience-based guidelines for laboratory services. For example, testing and applying algorithms or new technologies will result in effective patient management and population-based TB control.

To date, the draft report has been approved by the APHL Board of Directors, distributed to ACET for review, and presented to APHL, NTCA and participants at the 4th National Conference on Laboratory Aspects of Tuberculosis. However, the document will need to be endorsed by CDC, ACET, TB control programs, laboratory partners, scientific

organizations and policymakers for implementation and adequate funding. Implementation of the report will also be necessary to enhance training of clinicians, laboratorians, TB program staff and other health care providers; strengthen the APHL/ NTCA partnership; and develop assessment templates described in the three benchmarks. APHL is requesting assistance from CDC, NCET and other partners in jointly developing the cost assessment and laboratory services templates.

ACET commended APHL in developing an impressive and timely document. Most notably, laboratory services will be significantly improved by the jurisdictional approach outlined in the report. However, ACET made several suggestions for APHL to consider in revising the draft. The cost-effectiveness and cost-benefit data should be thoroughly reviewed. The report should recommend that AFB smears be used as a screening test with a two-hour turnaround time to obtain results. This approach will assist clinicians in quickly making judgments about next steps for patients with normal or abnormal chest x-rays.

More explicit language should be incorporated into the report because the current draft does not take a position on the recommendations. For example, network collaboration models highlighted in the document have both advantages and disadvantages, do not consider available bioterrorism resources, and do not advocate for regionalization. Consideration should be given to DTBE rather than APHL being responsible for the assessment of TB laboratory services. The evaluation would then be a routine, standardized and systematic component of surveillance.

CDC also made suggestions for APHL to consider. To "conduct a comprehensive assessment of TB laboratory services," a model developed by the Washington State Department of Health should be considered in which a cohort review was conducted to account for all patients who were diagnosed by a jurisdiction in any quarter. Outcome measures of interest for each patient were assessed and incorporated into the cohort review, such as the turnaround time between collecting specimens and obtaining results. The information can be used to determine capacity at the program level and potentially could be provided to public health laboratories. Although DTBE could be assigned responsibility for laboratory assessments, this effort would be more effective as a component of the cohort review. Data collected from the cohort review could then be used for surveillance. To "strengthen the APHL/NTCA partnership," NTCA's June 2004 workshop may focus on TB laboratory issues and universal genotyping. Because a national concerted effort has not been made for ten years to strengthen laboratory capacity, the meeting may present an opportunity for APHL to present the report and obtain formal endorsement from NTCA.

APHL made follow-up remarks to the discussion. APHL will not be directly involved with performing research on new blood tests to diagnose LTBI, but its members may

conduct studies in conjunction with program activities. After data are collected, APHL's role in this effort will be to determine the appropriate use for the QFT-TB test. APHL does not take a position in the report because state laboratories have limited knowledge of jurisdictional capacity at this time. Before public health laboratories can make changes in conducting business, comprehensive assessments of TB laboratory services must first be conducted to identify existing strengths and weaknesses. APHL will determine the feasibility of linking existing laboratory recommendations to guidelines for responding to potential bioterrorism events and identifying infrequent infectious agents. The two sets of recommendations are similar and could perhaps be incorporated into the laboratory assessments outlined in the APHL report or the cohort review model described by CDC.

ACET placed a motion on the floor to formally endorse and support the APHL report. ACET further recommended that CDC consider the APHL recommendations when revising its laboratory guidelines. The motion was properly made and seconded by voting members and was **unanimously approved** with no further discussion. ACET members were encouraged to submit comments on the APHL draft report to Ms. Paulette Ford-Knights.

Federal TB Task Force (FTBTF) Plan

DTBE Update. Dr. Michael Iademarco of DTBE conveyed that TB cases reported in the United States from 1982-2002 demonstrated an increase in an unprecedented resurgence. The TB epidemiology triggered the establishment of FTBTF in 1991 to develop a national action plan to combat multi-drug resistant (MDR) TB. Several federal agencies took actions in 1992-2002 to support FTBTF's efforts. CDC renewed the U.S. TB program and laboratory infrastructure by creating the Tuberculosis Trials Consortium and the Tuberculosis Epidemiologic Studies Consortium (TBESC). NIH initiated research in rapid drug screening; established the Tuberculosis Research Unit; published the Vaccine Blueprint in partnership with CDC and the Food and Drug Administration (FDA); presented TB academic awards; administered screening and treatment among intravenous drug users; and released AIDS/TB training grants.

HRSA increased collaboration between CHCs and departments of health and also instituted TB screening and care in partnership with DIHS. FDA addressed shortages in streptomycin and para-aminosalisylic acid; approved fixed-dose combinations; studied and approved nucleic acid amplification (NAA) tests; distributed the BCG vaccine document; approved the first-generation QFT-TB test; and established a new standard for purified protein derivative (PPD-S2). The Indian Health Service (IHS) responded to TB outbreaks and conducted screening. The Department of Veteran Affairs monitored TB care in its hospitals. The Federal Bureau of Prisons administered TB screening and

care. The U.S. Agency for International Development (USAID) provided global TB support.

After IOM released *Ending Neglect* in May 2000, both CDC and FTBTF issued reports to respond to the recommendations. FTBTF convened two meetings in 2000 and 2001 to develop its plan, revised and finalized the document, and obtained HHS-wide clearance in August 2003. The plan focuses on four of the IOM recommendations to maintain control, accelerate the decline, develop new tools and increase global involvement. In drafting the plan, FTBTF formed three breakout groups for services, financing and quality; targeted testing and treatment of LTBI; and needed research. The workgroups were charged with defining related federal activities and identifying lead and collaborating agencies to implement the plan.

In a face-to-face meeting in September 2003, FTBTF presented its response to *Ending Neglect*, reviewed progress to date, discussed distribution and implementation of the plan, and considered FTBTF's future role. The key strategies of the plan are for ACET and FTBTF to monitor progress of the IOM report goals; facilitate and coordinate regular information exchange by conference call; and convene an annual face-to-face meeting to review progress. ACET has agreed to monitor the IOM recommendation that called for assessing the impact of the *Ending Neglect* guidelines and measuring progress toward achieving TB elimination. CDC will develop objective indicators for this effort.

The FTBTF plan concluded that strategies and action steps compliment ongoing federal TB activities, but all initiatives cannot be implemented with current funding. Agencies should implement action steps as resources become available. To further address and advance coordination and more substantive issues, FTBTF agreed that three workgroups should be established to focus on maintaining support and accelerating the decline domestically; developing new tools and research; and implementing a global TB program and research. DTBE staff have been appointed to chair the workgroups. FTBTF will continue to be aware of several events in 2000-2003 that can lead to erosion, renewed complacency or new opportunities for TB, including the IOM report, President's Emergency Plan For AIDS Relief, Gates Foundation, global TB organizations, and FTBTF's future role.

NTCA Perspective. Ms. Kim Field is the ACET liaison representative for NTCA and also the NTCA President. She explained that NTCA's approach in addressing the FTBTF plan was to identify nine priorities for TB controllers, acknowledge barriers, and encourage collaboration among federal, state and local agencies in implementing the action steps. NTCA's criteria to prioritize actions were based on relevance to state and local programs, need, feasibility in terms of implementation and resources, and progress toward implementation. NTCA acknowledged that the federal funding gap is a

critical issue toward achieving TB elimination. NTCA's priorities in response to the FTBTF plan are as follows.

To maintain control, follow-up of immigrants and refugees arriving in the United States with suspected TB should be improved and optimized. Efforts should be made to improve and ensure the quality of TB examinations conducted by overseas panel physicians and domestic civil surgeons. Continuity of care should be facilitated for prisoners and ICE detainees across correctional facilities and communities in the United States, Mexico and other areas. Short- and long-term plans that are cross-jurisdictional and facilitate surveillance, case management and program evaluation should be developed for integrated systems. Public and private third-party payers and all other funding sources should be evaluated as mechanisms to increase third-party reimbursement for TB services.

To accelerate the decline, national recommendations or guidelines should be developed that define "close contacts" and also address challenges of TB investigations in foreign-born persons and social networks. Circulating TB strains should be characterized with DNA fingerprinting results. Efforts should be made to ensure implementation of CDC guidelines for preventing and controlling TB in high-risk populations or environments. Cultural competency, training and education should be provided to American Indian/Alaska Native health care workers. More emphasis should be placed on disseminating information to this population and improving contacts with IHS providers and TB control programs at state and local levels.

To develop new tools, less emphasis should be placed on the projected 50-year period for testing TB vaccines because a vaccine will not be a priority for the United States if the TB elimination recommendations are widely and effectively implemented. The importance of the QFT-TB test, NAA direct tests and other diagnostic tests should be underscored, but barriers to presently implementing these tests should be acknowledged. To increase global involvement, the significance of U.S. efforts to provide resources for international TB control should be highlighted, but inadequate funding to address TB in foreign-born persons who enter the United States must be considered as well.

NTCA noted several caveats in identifying its priorities. First, since CDC, DIHS, HRSA, NIH, NTCA and other groups have conducted successful TB control and elimination activities, models and best practices should be compiled into one system to prevent duplication of existing efforts. Second, none of the recommendations will be effective without a strong workforce of trained, educated and skilled health professionals. Third, a national effort should be undertaken to place TB higher on the list of priorities. For example, a survey administered in 2002 showed TB as a low priority among 37 local health jurisdictions in Washington State that responded. Fourth, stronger emphasis

should be placed on data management because paper forms, telephones and facsimiles are still used to track TB cases throughout the country. An electronic laboratory reporting system and a coordinated process for TB notification of refugees, immigrants, homeless persons and inmates are critically needed.

ACET's discussion focused on priorities NTCA identified in response to the FTBTF plan. First, an existing model for immunization and STD should be applied to TB to strengthen collaboration with IHS. A CDC public health advisor is housed in IHS and serves as a national coordinator between the two agencies. Second, significant resources are being allocated globally for infectious disease control, but funding is not adequate to control or eliminate TB in the United States. A suggestion was made for local programs to take stronger actions in leveraging other sources of funding, such as third-party billing to screen and treat persons with LTBI, Medicare for undocumented individuals with active TB and Medicaid. HRSA will explore the possibility of CHCs using Medicaid funds to focus on targeted testing and treatment.

Third, civil surgeons fall under the purview of DOS rather than HHS. As a result, public health agencies are extremely challenged by evaluating civil surgeons in terms of quality of services provided and types of data collected from immigrants. Fourth, the IOM report called for PPD screening of all immigrants prior to U.S. entry, but assurances should first be made that the B notification, screening and follow-up process covers TB suspects. For example, LTBI green cards are not included in the evaluation; screening is not mandatory for TB suspects entering the United States. ACET should consider the possibility of issuing a formal statement to recommend follow-up of TB suspects since these persons are a public health hazard. Most notably, individuals with a B1 classification have a high rate of active TB of at least 6%. DIHS will explore whether the Department of Homeland Security's (DHS) Office of Science and Technology can play a role in addressing the legal aspect of TB among immigrants.

CDC also made comments in response to the NTCA priorities. First, CDC differs with NTCA's perspective on TB vaccines. For example, a vaccine that offers secondary protection to persons with LTBI and prevents active TB would be enormously beneficial to ~12 million persons in the United States with LTBI. Second, TB has been a qualifying disease under Medicaid since 1993, but only eight states have incorporated this provision. Efforts should now be made to revisit and widely promote TB Medicaid entitlement programs to ensure states are aware of and access this funding source. Third, HHS has responsibility for developing screening criteria, immunization practices and other guidelines to be used by civil surgeons. However, CDC acknowledges that its oversight of compliance with guidelines is limited since DOS appoints civil surgeons. Although several recommendations have been made over the years to develop a certification process for civil surgeons, CDC welcomes additional input from ACET's Foreign-Born TB Workgroup on this issue.

2004-2008 National Strategic Plan. Mr. John Lewis, of the Francis J. Curry National Tuberculosis Center, reported that the purpose of the strategic plan is to engage stakeholders, secure consensus and promote coordinated action leading to results. The first five-year plan for 1999-2003 was developed in 1998 and reflected national collaboration between DTBE and three Model TB Centers (MTBCs). A secretariat was assigned to address administrative and logistical issues and expertise was solicited from numerous stakeholders throughout the country. National goals proposed by the group drew national attention, such as the IOM recommendation to fully implement and fund the strategic plan.

The second five-year plan for 2004-2008 reflects the same collaboration and overall process as the previous plan, but the national goals were confirmed and strategic objectives were proposed. The 2004-2008 strategic plan will examine the current status of TB training and education (T&E) by focusing on several areas. For audiences, a concentric circle approach was taken to establish priorities. TB programs were identified as the core audience for TB T&E because these groups have frequent contact with patients and are responsible for TB control and treatment. Staff who serve patients at high risk for TB have other than frequent contact and were identified as a secondary audience for TB T&E.

In addition to "frequent" or "other than frequent" contact with TB patients, high, medium or low incidence also plays a role in identifying audiences for TB T&E. A dedicated model can be implemented in high-incidence areas with a TB controller, program manager, case managers, outreach workers, laboratory personnel and clinicians. A generalist model can be used in low-incidence areas with health officers, private physicians, public health nurses, private laboratories and state level support. A compounded approach can be taken by groups with other than frequent contact with TB patients, such as correctional facilities, homeless shelters, HIV programs, drug addiction programs and foreign-born organizations.

To determine the penetration of TB T&E, three national surveys were administered in 1998-2003. Responses from NTCA, the National Tuberculosis Nurse Consultant Coalition, and the Tuberculosis Education and Training Network showed that 44%-67% of 112 TB controllers, managers, physicians, nurses, disease investigators and other staff agreed TB T&E penetration is occurring. Of 112 laboratory personnel, local health officers, public health nurses and civil surgeons, <25%-33% agreed with the statement. Less than 25% of 112 program staff in correctional facilities, alcohol and drug treatment programs, HIV/STD programs, homeless shelters, hospitals and nursing homes agreed TB T&E penetration is occurring. The surveys showed that TB T&E has penetrated the core constituency, but other key groups have a continuing need.

For TB T&E implementation, delivery systems are decentralized and frequently interact; vary at national, regional or local levels; differ based on development or delivery of training and materials; and depend on whether TB is or is not a dedicated activity. Despite the diversity in delivery systems, opportunities exist for greater coordination because several groups are cornerstones in implementing TB T&E. DTBE and the MTBCs are influential trainers at all levels; state health departments are essential trainers in high-incidence areas; and many national organizations and professional societies are central trainers at national, local and regional levels. Local health departments also serve as delivery systems by providing TB T&E to general training staff and medical personnel. These findings are supported by the 1998 and 2003 national surveys in which CDC, health departments and MTBCs were cited as the sources used most often for TB training or events.

Eight objectives were formulated to measure future directions and determine the potential for the 2004-2008 strategic plan to serve as a change agent. A steering committee, six workgroups and a secretariat were established for this effort. The strategic plan goals broadly focus on collaborations and TB T&E resources, but the objectives were developed with more specific and measurable outcomes, feasible approaches and a defined five-year time-line. Categories of stakeholders were addressed in creating the objectives, but detailed actions were not described due to the diversity and large number of audiences. The objectives address education for medical and health care students, core competencies, TB T&E opportunities and materials, cultural competency, communication and information networks, funding and implementation, and international TB T&E efforts. The desired outcome, specific strategies and best group for implementing the eight objectives are fully detailed in the strategic plan. A partial draft was distributed to ACET for review.

Efforts will soon be undertaken to promote, distribute and present the strategic plan, request endorsement, and ask key stakeholders to participate in implementing the document. Advocates will also be asked to assist in promoting and guiding TB T&E efforts over the next five years to control and eliminate TB. A list of key agencies and other groups that should receive presentations of the strategic plan is currently being developed. Overall, the strategic plan should only be viewed as a tool because infrastructure is needed to support the use of the document. A decentralized group of stakeholders can then jointly use the strategic plan and a solid infrastructure to improve the status of TB T&E. The 2004-2008 TB T&E strategic plan is nearly complete and should be published in early March 2004. The final document will be ~200 pages.

Overview of the Tuberculosis Education and Training Network (TBETN). Ms. Maria Fraire of DTBE explained that the initiative was established in 2001 in response to a recommendation from the 1993-2003 TB T&E strategic plan. The goals of TBETN are to build, strengthen and maintain collaboration among TB T&E partners; provide a

mechanism to share resources and avoid duplicating efforts; develop, improve and maintain access to resources; provide up-to-date information about courses and initiatives; and assist TBETN members in building skills. TBETN is designed to develop a cadre of TB educators and trainers who have improved skills and abilities, knowledge of available resources, and capacity to serve as a resource for outbreaks, implementation of new guidelines and other high-priority needs.

The TBETN membership was initially limited to primary and secondary members in states, big cities and U.S. territories, but the current membership is open. As of January 2004, TBETN had 394 members. Active members have voting rights, receive priority registration for activities and may serve on subcommittees. Information-only members receive updates about TBETN via e-mail and do not have the privileges of active members. No fees are charged for TBETN membership. TBETN members represent TB organizations, groups and programs in the United States and several countries. The TBETN steering committee and three subcommittees are instrumental in guiding several activities.

In the "Adopt-a-State" project, the current TBETN database is being reviewed to identify gaps in membership and recruit new members. The TBETN brochure, poster and other marketing materials are displayed at exhibits, conferences and other events. The materials are also used to promote awareness about TBETN and recruit new members. A contest is being held to design a pin that will identify TBETN members. Cultural competency resources are being compiled; tools to evaluate resources are being reviewed; and TBETN articles are submitted to the *TB Notes Newsletter* that is published quarterly by DTBE. The TBETN section of the newsletter highlights members, provides cultural competency tips and refers readers to other TB T&E-related articles.

The first annual TBETN conference in 2001 focused on culture, language and literacy in TB T&E. The 70 participants attended skill-building sessions to enhance knowledge in conducting needs assessments, developing culturally-appropriate materials and locating resources. A business meeting was also held at the conference to provide networking activities, identify TB T&E barriers, develop proposals to overcome barriers, and discuss the future of TBETN. The second conference in 2002 focused on reaching key audiences through innovative TB T&E methods. The participants strengthened skills in partnership techniques, needs assessments, development of appropriate products, incorporation of technology into TB T&E, and evaluation of products. Local TB programs were also provided an opportunity to highlight projects.

The third conference in 2003 focused on new directions for TB education. The 100 participants attended a business meeting as well as plenary and breakout sessions to build skills. The fourth conference is being planned and is tentatively scheduled for

August 2004 to focus on capacity building and the systematic health education planning process. The FY'05 cooperative agreement will impact TBETN because grantees will be awarded funds specifically earmarked for TB T&E. Grantees will be required to designate a focal point for TB T&E, ensure membership in TBETN and develop a training strategy plan post-award. Technical assistance to grantees in the development of a training strategy will be provided via TBETN. Additional details about TBETN membership and activities can be obtained from DTBE by telephone, mail or Internet.

Open Discussion

ACET first focused on the TB T&E 2004-2008 strategic plan. Recipients of the Substance Abuse and Mental Health Services Administration (SAMHSA) block grant are required to make provisions for TB care, treatment, counseling and testing for persons who present for substance abuse counseling and treatment. As a result, efforts should be made to widely promote and distribute the strategic plan to SAMHSA training centers and other grantees. The strategic plan should not define specific skill sets for certain audiences or locations, such as "providers who serve high-risk TB patients." Instead, TB T&E should be broadly implemented to all providers, including those who treat very few TB cases. Regardless of whether a practice is located in a low-, medium- or high-incidence area, all clinicians should have the ability to conduct a TB risk assessment.

To assist in maintaining long-term support, TB T&E volunteers and advocates who participated in the 1999-2003 strategic plan should be retained as workgroup members or involved in another capacity in the current effort. The Centers for Medicaid and Medicare Services should be considered as a partner in implementing the TB T&E strategic plan because the agency develops quality indicators for groups that develop Medicaid and Medicare contracts for managed care organizations. Since health care groups must adhere to quality indicators to receive reimbursement, this requirement may drive the demand for TB T&E.

ACET's second area of discussion focused on its role in the development of the MTBC program announcement, such as providing CDC with language to include in the document. ACET acknowledged that its previous recommendations led to CDC establishing priorities for TB among blacks in the Southeast, TB along the U.S.-Mexico Border, TB disparities among foreign-born persons and other issues. In the interim of submitting formal comments, ACET made several suggestions for CDC to consider in developing the MTBC program announcement. First, MTBCs should have stronger capacity in medical consultation in the context of formalizing and obtaining feedback from providers who receive these services.

Second, the new MTBC program announcement should promote broader collaboration to implement specific strategies across jurisdictions rather than a single geographic area. For example, a MTBC could be located in the U.S.-Mexico Border region. Third, MTBCs should expand partnerships beyond TB control programs to include individuals, private providers, communities, CHCs, agencies and other groups at the local level that can assist in reaching populations at high risk for TB. MTBCs should ensure that local outreach efforts are considered early during the design of activities. Fourth, MTBCs should consider replicating the IHS pilot project in which providers take a web-based training program with continuing medical education (CME) credits and are graded on a monthly basis in screening, treatment and other areas.

ACET's third area of discussion focused on TB activities along the U.S.-Mexico Border. ACET acknowledged that BHC and TATB initiatives are critical to the success of many TB programs and organizations throughout the United States. A suggestion was made for ACET to formally address public health staff who attempted to transport medication for MDR-TB patients across the Border, but were detained by immigration officials. International law currently prohibits the transport of these goods. Several members did not support the suggestion because a formal motion may be misinterpreted as ACET's endorsement to violate current laws in the provision of TB treatment and care. Other members also did not agree because the suggestion focuses on immigration and customs laws that are beyond ACET's purview.

CDC made follow-up remarks to ACET's deliberations. The TB T&E strategic plan should be presented to FTBTF because its membership represents various federal agencies and implementation of the eight objectives will require resources. CDC also clarified ACET's role in the development of the MTBC program announcement. Input from ACET would be valuable in this effort because ACET's formal recommendations on TB in low-incidence areas led to CDC awarding funds to a MTBC to focus on this issue. The MTBC program announcement is scheduled to be released in March 2004; CDC will consider general language from ACET prior to this time. Examples of "general language" include criteria to address training needs for TB elimination or the 2004-2008 TB T&E strategic plan objectives. However, ACET cannot be involved in the process to review and select proposals submitted for funding. ACET also cannot review the MTBC program announcement prior to its public release because some members may submit applications for funding.

The existing MTBCs are charged with focusing on optimal patient care, providing TB T&E, implementing innovative solutions to TB control problems, and making medical consultative services available to others throughout the country. CDC has continually monitored progress of the MTBCs, but efforts are now being made to strengthen capacity in the provision of TB T&E and medical consultative services. The implementation of innovative solutions will not be a requirement in the upcoming

program announcement. Another new feature in the March 2004 program announcement is that MTBC funding will be incorporated into the cooperative agreement to 68 areas and separated from the TB Prevention and Control cooperative agreement. This approach will provide DTBE with more flexibility to operate at different time-lines.

For the previous cooperative agreement, CDC solicited input from NTCA to obtain perspectives from TB control programs that are not part of MTBCs. The intent of the new cooperative agreement will be to build on the existing "model center" approach, but advance somewhat beyond this strategy. For example, CDC has considered the possibility of expanding MTBCs to "TB Training and Education Centers," the "TB Education and Training Network" or a replication of the STD model. Regardless of the model used, MTBCs will be placed in areas to effectively implement the 2004-2008 TB T&E strategic plan on a regional rather than local level. CDC is aware that the ideal outcome would be six MTBCs geographically dispersed throughout the country, but funding for four or five centers will probably be the realistic outcome. All grantees of the CDC TB cooperative agreement and HRSA-funded CHCs are eligible to submit applications in response to the MTBC program announcement.

In terms of collaborations at the local level, CDC acknowledges that MTBCs must make stronger outreach efforts in local communities, but the TB T&E strategic plan should present an opportunity for MTBCs to better meet the needs of CHCs, private providers, hospitals, national organizations and professional groups throughout the country. In the interim, however, CDC is currently considering strategies to use its TB outbreak response plan to improve outreach efforts to the mass media and local areas and also to enhance TB T&E to local providers where TB outbreaks occurred. Both the TB T&E strategic plan and MTBC program announcement will address targeted training to emergency room doctors and other specific providers, but collaboration from professional associations of physicians, nurses, physician assistants and other front-line health care providers will be needed to promote TB T&E among these groups.

ACET took actions to conclude its deliberations. A motion was placed on the floor to ratify and reaffirm the 2004-2008 TB T&E strategic plan as presented on February 4, 2004 and also to encourage CDC and its partners to move forward on fully implementing the plan. The motion was properly made and seconded by voting members, but agreement was reached to delay taking action on this issue until the full strategic plan was distributed, reviewed and discussed by ACET at the next meeting. **The motion was withdrawn.**

ACET agreed to the following process to provide CDC with general language on the MTBC program announcement. Individual members will submit the first set of comments to Ms. Paulette Ford-Knights, the Committee Management Specialist, by

February 11, 2004 for distribution to the full ACET. The second set of comments will be due to Ms. Ford-Knights by February 16, 2004. Dr. Kawamura will review the second set and forward the comments to Dr. Castro by February 18, 2004.

A motion was placed on the floor for ACET to endorse and encourage BHC's ongoing efforts to remove existing barriers to optimal care of persons with TB along the U.S-Mexico Border. The motion was properly made and seconded by voting members, but agreement was reached to delay taking action on this issue until ACET's 2002 statement and recommendations on HHS's collaboration with the Department of Justice's Immigration and Naturalization Service (INS), now DHS/ICE, could be distributed to and reviewed by ACET on the following day. **The motion was tabled.**

With no further discussion or business brought before ACET, Dr. Kawamura recessed the meeting at 4:55 p.m. on February 4, 2004.

Status Report on QFT-TB Studies

In the temporary absence of the ACET Chair, Dr. Valdiserri reconvened the meeting at 8:39 a.m. on February 5, 2004 and yielded the floor to the first presenter. Dr. Iademarco reported that a new TB test is needed because the tuberculin skin test (TST) is often not read; presents clinical, public health and cost issues; leads to false-positive results due to BCG vaccination and non-tuberculous mycobacteria; and contains inherent inaccuracies in terms of TST placement and reading. QFT is a test for *M.tb* infection and depends on interferon-gamma that is an important cytokine in pathogenesis. The QFT-TB test is an *in vitro* whole-blood assay that measures interferon-gamma release from lymphocytes after incubation with *M.tb* antigens.

Performance of the QFT-TB test depends on finding *M.tb* infection, differentiating between LTBI and TB disease, and having an accuracy rate better than or equal to TST. The QFT-TB test must also contain desired sensitivity and specificity relative to TST. One of the most significant limitations in pursuing research on the QFT-TB test is the absence of a gold standard. Longitudinal studies were conducted in the 1950s and 1960s with large cohorts to determine TST's capacity to diagnose *M.tb* infection, but this type of research is not practical in the current environment. Sensitivity can be extrapolated from culture-confirmed cases of TB disease, while specificity can be extrapolated from persons with minimal risk. The TST response increases with the treatment of TB disease, but preliminary data show that the QFT-TB test decreases. In terms of LTBI, the best approach available at this time is to conduct an analysis to compare to or agree with TST due to the absence of a gold standard.

The first-generation QFT-TB test was approved by FDA in November 2001 and was based on PPD antigens. The most significant limitation was that the first-generation QFT-TB test could not be used in contact investigations or other settings where TB was suspected. The second-generation QFT-TB test depended on TB-specific antigens, such as ESAT-6 and CFP-10. The epitope for these antigens is present in *M.tb*, but absent in BCG and nearly all non-tuberculous mycobacteria. FDA's review of the second-generation QFT-TB test is pending until the CDC-Navy trial and other studies are completed. The third-generation QFT-TB test is an "in-tube" assay that improves the process of drawing blood, transporting the specimen within 12 hours to a 37-degree water bath for incubation, and forwarding the blood to a qualified laboratory for processing within one to two weeks. Mtb7.7 is another antigen that has been added to the third-generation QFT-TB test to further enhance sensitivity.

Guidelines for using the QFT-TB test to diagnose LTBI were published in the January 31, 2003 edition of the *MMWR Reports and Recommendations* (*R&R*), but several studies are still underway. Preliminary data from a Japanese trial using the second-generation QFT-TB test in a cohort of 116 persons with culture-confirmed TB prior to treatment showed the following results. Sensitivity of the first- and second-generation QFT-TB tests was 82% and 89%, respectively, while TST sensitivity was 66% in a subset of 72 persons. In another cohort of 218 nursing studies who were BCG vaccinated in childhood, specificity of the first- and second-generation QFT-TB tests was 56% and 98%, respectively, while TST specificity was 35% in a subset of 113 persons. Subsets of the cohorts were used to compare TST sensitivity because a Japanese version of PPD was administered in the study. The Japanese trial is closed and the data have been analyzed and submitted to FDA and peer-reviewed journals.

CDC is also conducting a series of studies on TST, the ELISpot, and first-, second- and third-generation QFT-TB tests. The ELISpot is an assay similar to the QFT-TB test, but is not yet commercially available. To date, 24 of 200 patients have been enrolled in the trial to determine sensitivity in untreated TB patients; 650 patients will be enrolled in February 2004 to analyze specificity in a low-risk population. This trial is a component of a sub-study among 820 Naval recruits. Efforts will be made to measure and correlate the level of exposure with the frequency of reactivity. An analysis of relationships among the tests may produce adjunctive evidence to assist in determining whether the QFT-TB test is similar to or better than other tests. To date, 643 of 1,250 contacts have been enrolled for this study. To analyze issues related to quality control, process and ability to reproduce, 505 of 554 QFT-TB tests have been repeated. This study will focus on TST's effect on the QFT-TB test and the natural history of converting with the QFT-TB test after exposure.

CDC's study in Ho Chi Minh City among 1,200 Vietnamese visa applicants is underway. TST and first- and second-generation QFT-TB tests are being compared to address

sensitivity based on abnormal chest x-rays and AFB-positive sputum smear. LTBI prevalence is being studied under a TBESC task order in four high-risk populations: HIV infection at presentation, homeless persons, newly arriving refugees, and clients in drug treatment programs. The sub-studies are being conducted in Atlanta, North Carolina and Seattle and the protocols are currently being reviewed and revised by an Institutional Review Board (IRB). CDC is performing a small study to particularly focus on specificity of the QFT-TB test and non-tuberculous mycobacteria. The analysis will be based on data collected from 40 cases and 40 controls after an outbreak of *M. fortuitum* infection occurred in a nail salon. Enrollment is underway and the study protocol may be adapted in the future for other non-tuberculous mycobacteria outbreaks.

TBESC developed a diagnostics initiative to facilitate improvements of tests for TB infection and disease by initially focusing on enhanced versions of the second- and third-generation QFT-TB tests; providing infrastructure and capacity to conduct the trials; and assessing the utility of new tests. DTBE ranked this research with the highest priority, but no funding has been allocated to date for the activity. However, efforts may be taken to advance the initiative because the Gates Foundation is funding a memorandum of understanding between CDC and the Foundation for Innovative New Diagnostics. On the one hand, data are increasingly showing significant promise for the QFT-TB test in comparison to TST. The QFT-TB test also represents an important step in producing a new diagnostic tool that can impact LTBI in the United States. On the other hand, technology is rapidly changing, studies on the QFT-TB test are difficult to integrate into outbreak settings, and investments in this research have been insufficient to date.

ACET made several comments on the QFT-TB trials. Consideration should be given to revising the guidelines on use of the first-generation test in contact investigations since baseline data have been collected for this setting. The recommendations should also be reevaluated because the Japanese study showed improved sensitivity and specificity of the QFT-TB test in comparison to TST. ACET noted several populations that were excluded from the QFT-TB trials. Since ~10 million persons pass through correctional facilities each year who are disproportionately affected by TB and require TST, this population should be included. Children are important in TB control because this group is at highest risk in contact investigations. Moreover, persons who are BCG-vaccinated at birth may have a relatively small cumulative risk of exposure compared to adults. International groups should be considered as a cohort in future QFT-TB trials to leverage funding for the HIV/TB package of care and increase support for TB at the global level.

CDC made follow-up remarks to ACET's deliberations. The Japanese data are very promising, but the study should be replicated elsewhere before the guidelines are

revised due to differences in TST use between the United States and Japan. The guidelines do not recommend the first-generation QFT-TB test for use in contact investigations or an assessment of TB disease because earlier studies were flawed in terms of insufficient sample sizes and lack of precision. Preliminary data from the second- and third-generation QFT-TB tests indicate that sensitivity will be adequate with respect to TB disease, but this finding cannot be confirmed until all analyses are completed. In terms of infection control, large facilities could probably introduce the first-generation QFT-TB test during a one- to two-year evaluation phase of administering both TST and QFT. Gradual integration of the first-generation QFT-TB test into health care screening would most likely result in cost savings to large facilities. The current guidelines support this approach.

CDC agreed that other groups should be included in QFT-TB trials, but several challenges must be considered. For example, obtaining an IRB-approved protocol for the corrections population will be extremely difficult. Children and immunocompromised patients are important groups to consider, but settings with potential TB disease and BCG-vaccinated persons have been established as priorities. International groups would advance specificity analyses given the high prevalence of TB disease, LTBI and HIV at the global level, but obtaining resources for research in this environment will be extremely challenging.

CDC also provided responses to specific questions. First, CDC will confirm whether the ELISA assay is specific for interferon-gamma. Second, the QFT-TB test is a relatively simple ELISA assay that should not cause problems in laboratories if batches are of reasonable volume. Laboratories may have the ability to use specific templates based on the volume of a specific batch, but the data are too preliminary at this point to make this conclusion. Third, current studies of the QFT-TB test are focusing on age and gender, but sample sizes are not sufficient to analyze race/ethnicity. However, this issue will be addressed in expanded trials.

Status Report by the Foreign-Born TB Workgroup

Dr. Michael Fleenor, the Workgroup Chair, reported that the workgroup held four conference calls after being established and charged during the last ACET meeting. The members identified 18 major themes to address, but efforts are now being made to prioritize these issues and assign topics to specific members. The 1998 guidelines as well as the CDC and FTBTF responses to the IOM report will serve as data sources to direct the workgroup's deliberations. The documents will be reviewed to determine current knowledge and activities, gaps in current knowledge, and future research needs. The workgroup is aware that its deliberations may result in a revision of the 1998 guidelines. The workgroup plans to make a more substantive report during the next

ACET meeting since process issues have been addressed. ACET and CDC commended Dr. Fleenor for his diligent efforts in organizing and leading the workgroup.

ACET Business

Dr. Kawamura entertained a motion to accept the previous meeting minutes. The motion was properly made and seconded by voting members. There being no changes or further discussion, the October 1-2, 2003 ACET Meeting Minutes were unanimously approved.

In response to Dr. Kawamura's request, ACET proposed the following agenda items to be added to the ongoing list of topics.

- Status report on QFT-TB trials.
- Update on the TB T&E strategic plan.
- Status report on the TB control statement.
- Presentation on key outcomes from the 2004 World TB Day.
- BHC update on the cross-Border transport of goods and other Border health initiatives.
- Update on foreign-born TB issues: workgroup report; overview by the Division of Global Migration and Quarantine on overseas TB screening and treatment for immigrants and refugees; and presentation of ICE's formal agreement to address detention and removal issues if the agreement is finalized.
- DTBE review on programmatic activities: TB among blacks in the Southeast; capacity to test and identify persons with TB infection or disease; completion rates for active TB and LTBI; the TB elimination initiative; LTBI through targeted testing and contact investigations; TB funding allocations; and TB outbreaks in the context of responses, current status, lessons learned and future needs at the local level.

ACET concluded its business by bringing closure to several outstanding issues. First, TB funding allocations and TB research will be priority items to place on the next agenda. Second, CDC agreed to make every effort to electronically distribute supporting materials and other background documents to ACET prior to meetings. Third, Dr. Kawamura will forward ACET's letter to the HHS Secretary to the NTCA President for broader distribution to NTCA members. The letter focused on TB budget issues and the need to place TB on the list of health disparities for minorities. DTBE will also circulate the letter to the Southeast TB consultation attendees, but Dr. Kawamura will draft a companion letter to briefly outline ACET's communication with the HHS Secretary on these issues.

Fourth, **the motion that was tabled on the previous day was withdrawn** and replaced with the following language. ACET should endorse and encourage BHC's ongoing efforts to remove existing barriers to ensure optimal care of persons with TB along the U.S-Mexico Border, such as the transport of medications, specimens and equipment. The motion was made and properly seconded by voting members. ACET's 2002 recommendations and statement were distributed to guide the discussion on the motion, but several members noted that the documents focus on active TB cases in INS (now ICE) custody and does not address specific issues outlined in the motion on the floor. To resolve this concern, agreement was reached for Dr. Kawamura to send a letter to the BHC Executive Director expressing ACET's support of the motion; the letter could then be more broadly distributed to BHC members. The motion was **unanimously approved** with no further discussion.

Overview of the President's Emergency Plan For AIDS Relief (PEPFAR)

Dr. Eugene McCray, the GAP Director, explained that the President announced the initiative on January 28, 2003. PEPFAR targets 14 countries to prevent seven million new HIV infections; treat two million HIV-infected persons; and provide care for ten million HIV-infected individuals and AIDS orphans. However, all 75 countries where the U.S. government has bilateral HIV/AIDS programs are defined as "PEPFAR countries." Of the 14 target PEPFAR countries, 12 are in Africa and the remaining two are in Guyana and Haiti. The request to include a 15th country in PEPFAR has not been confirmed at this point, but Brazil, China, India and Russia have been mentioned as possibilities.

Public Law 108-25 authorized a Global AIDS Coordinator (GAC) for PEPFAR and required a comprehensive five-year global HIV/AIDS strategy to be developed in February 2004. An initial draft of the strategy is currently being reviewed and will be reported to Congress. Mr. Randall Tobias was sworn in as the GAC in October 2003 and was given the rank of Ambassador. He reports directly to the Secretary of State and is responsible for oversight and coordination of all U.S. government resources and international activities to combat the HIV/AIDS epidemic. Ambassador Tobias visited CDC in January 2004 and was given briefings on global TB and other issues.

Although PEPFAR focuses on AIDS relief, the legislation includes direct language for TB. The need to treat and control TB using the directly observed treatment short-course (DOTS) was noted. TB control was emphasized as a major objective in the foreign assistance program in order to detect at least 70% of infectious TB cases and cure at least 85% of detected cases. The President's role in coordinating the Global Fund, World Health Organization (WHO) and other groups to develop and implement a

comprehensive TB control program was defined. The President's role in prioritizing activities that increase DOTS coverage and treatment as well as MDR-TB treatment with the DOTS-plus strategy was also delineated. Funding allocations to global TB drug facilities, Stop TB and the Global Alliance for TB Development were described. Beginning in FY'05, nearly all international HIV/AIDS, TB and malaria activities will be under the purview of the GAC.

Of the $15 billion that will be allocated to PEPFAR over five years, $10 billion are new dollars and the remaining $5 billion are existing funds to CDC, NIH, USAID and other federal partners. The new $10 billion includes $2.4 billion for prevention of mother-to-child transmission (PMTCT) and the existing $5 billion includes $60 million for PMTCT allocated to CDC in FY'03. On January 22, 2003, the Senate approved an omnibus spending bill to include $2.4 billion for PEPFAR in FY'04. In FY'04 appropriations, CDC received a core budget of $144 million and an additional $150 million for the PMTCT initiative. The GAC Office will allocate an additional $150-$200 million to CDC, but the exact amount has not yet been determined. Although GAP funding has increased each year since FY'00, the core budget from FY'02-FY'04 has remained the same. Non-PEPFAR countries are receiving less dollars due to the flat funding; CDC is currently discussing this issue with the GAC Office.

Of all PEPFAR funds, 55% will be used for treatment, 20% for prevention, 15% for palliative care, and 10% for orphans and vulnerable children. Of the treatment funds, 75% will be targeted to purchase and distribute anti-retroviral (ARV) drugs. As a result, only 25% will be available for opportunistic infections, preventive therapies and other treatment issues. PEPFAR policy guidance states that the least expensive and safest ARV drugs currently available must be purchased and approved by a U.S. regulatory agency or an international "like body." Until more explicit guidance is developed, the partner agencies can only purchase brand drugs because only a few regulatory agencies qualify for the PEPFAR policy guidance. Of the prevention dollars, 33% will be designated for abstinence until marriage programs.

The legislation clearly states that PEPFAR is to be implemented as a single U.S. government program; coordinated by the GAC Office; based on the existing structure of the International Mother and Child HIV Prevention Initiative established in July 2003; coordinated with other donors at headquarters and country levels; and conducted based on a "network model" of health care delivery. The network model is designed with large medical centers in capital cities for major referrals, regional medical centers for complex problems and sophisticated diagnoses, and periphery medical centers for minimum care. Separate country plans are currently being developed to specify roles and responsibilities for CDC, USAID and other partner agencies. Although these plans should ideally be complimentary, the GAC will require, sign and approve a

comprehensive U.S. government plan beginning in FY'05 to be endorsed by country ambassadors.

Several tracks have been established to plan and effectively implement PEPFAR. Track 1 covers activities that can be rapidly started, central RFAs to compliment country plans, and recruitment of new partners with multinational reach. CDC, HRSA and USAID will be responsible for ARV treatment, blood safety, injection safety, behavior change plus abstinence, and orphans and vulnerable children. After the Track 1 RFAs were released in December 2003, proposals were reviewed in January 2004 and recommendations for funding were made to the GAC Office. The successful applicants are expected to be announced soon. Track 1.5 covers activities that can be rapidly started and new or expanded country-based initiatives funded in January 2004. Of the 14 PEPFAR countries that applied for $228 million, nearly all were approved by the GAC Office. More than 50 of the proposed activities will be housed in CDC.

Track 2 covers comprehensive and integrated country plans that are due by March 31, 2004. PEPFAR core planning teams were formed and will visit the 14 PEPFAR countries in February-March 2004 to provide technical assistance in developing the Track 2 plans. A follow-up meeting will be held in April 2004 in Africa to review the Track 2 plans and identify next steps. All PEPFAR countries are required to submit five-year plans for the overall initiative by September 31, 2004. The PEPFAR core teams include the GAC and staff from CDC, HRSA, USAID and the Department of Defense. The core teams are charged with linking to at least three countries and coordinating activities between the GAC and agencies; initial site visits are currently underway.

In addition to the tracks, ongoing work stream activities have also been created to implement PEPFAR. The strategic information work stream will cover surveillance, informatics, monitoring, evaluation, and targeted assessments by core teams to identify mechanisms for collecting data and measuring PEPFAR goals. The GAC Office has identified a staff member to focus on the evaluation component, but CDC will play a major role in this effort. The template for country system plans and other evaluation procedures previously developed by CDC will be used in PEPFAR.

Since evaluation will involve a collaborative effort among several U.S. government and international partners, efforts are now being made to harmonize indicators that will be assessed. Progress in reaching established targets and capacity in prevention, care, treatment and other program areas are some of the indicators that will be evaluated under PEPFAR. The partners have identified nearly 100 indicators to assess, but targeted evaluation studies will need to be performed to prioritize these issues.

Work streams have also been developed for procurement and program services. However, the remaining two work streams for communication and human resources

need the most attention, but are receiving the least amount of funding. The GAC Office oversees all communications regarding international HIV/AIDS activities supported by the U.S. government, but the partner agencies are extremely challenged by this requirement since the office currently has no staff. Human resource development in the PEPFAR countries is another major barrier because no staff have been designated to address this issue. Capacity building to facilitate treatment, delivery of ARV drugs and other training needs of country physicians, nurses and para-professionals are major components of PEPFAR. CDC has been asked to detail a staff member to the GAC Office to take the lead on human resources and capacity development.

Overall, PEPFAR presents an unprecedented opportunity to impact the global AIDS epidemic. Resources will continue to be allocated based on success in implementing the initiative. PEPFAR is a highly visible, fast-paced and complex program that is designed as a coordinated single approach within the U.S. government. Although PEPFAR is clearly focused on 14 countries, plans to address program growth in non-PEPFAR countries have not been articulated to date.

CDC provided additional details about PEPFAR in the context of ACET's concerns about significant global investments. Although PEPFAR is viewed as a high priority throughout HHS and CDC, the initiative is not intended to erode previous progress. For example, the PEPFAR country plans are required to outline a process for PEPFAR activities to compliment existing initiatives supported by the Global Fund, World Bank and other donors. Discussions are underway with WHO to identify a strategy to closely coordinate PEPFAR with the "3 by 5" initiative in which three million persons would be placed on ARV drugs by 2005. Efforts will be made to coordinate PEPFAR with the Global Fund for AIDS, TB and Malaria, particularly since the HHS Secretary serves as the Global Fund Chair. CDC and USAID will continue to play a major role in supporting Global Fund applications and assisting countries in implementing Global Fund activities.

Research dollars will be set aside in PEPFAR funding to ensure that international basic science and targeted evaluation studies initiated by GAP will continue and will be directly applied to in-country programs. Discussions are underway about the types of research initiatives that can be incorporated into PEPFAR. CDC was extensively involved in the development of WHO's new interim policy on collaborative efforts between TB and HIV programs. During country visits to provide guidance and other technical assistance, CDC emphasizes the need for countries to consider the WHO policy while developing the PEPFAR one- and five-year plans.

DTBE distributed a letter to TB controllers in January 2004 announcing updated guidelines for the use of rifamycin in HIV-infected patients taking protease inhibitors or non-nucleoside reverse transcriptase inhibitors. The updated guidelines will be an extremely important technical consideration in introducing ARV drugs to PEPFAR

countries with high TB prevalence. Discussions are underway about the possibility of publishing the updated guidelines as an *MMWR R&R* with CME credits, but the document can now be accessed on the NCHSTP web site.

Closing Session

The next ACET meeting is tentatively scheduled for June 2-3, 2004; June 23-24, 2004 was selected as an alternate date. DTBE will poll the members by e-mail to confirm this date.

With no further discussion or business brought before ACET, Dr. Kawamura adjourned the meeting at 11:12 a.m. on February 5, 2004.

I hereby certify that to the best of my knowledge, the foregoing Minutes of the proceedings are accurate and complete.

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Date

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L. Masae Kawamura, M.D.
ACET Chair